

The Maryland Board of Pharmacy Public Minutes - November 17, 1999

The Public meeting was called to order 9:53 A.M.

In attendance were President Stanton Ades, Commissioners: Wayne Dyke, Ramona McCarthy Hawkins, Melvin Rubin, Jeanne Furman, Laura Schneider, David Russo and Dr. Raymond Love; Board Counsel, Paul Ballard; Board Staff: PCO Michelle Andoll, Secretary Wendy Wilson, and PEP Student Andrew Rohrbaugh.

Commissioners absent: Rev. William Johnson, Barbara Jackson, Donald Yee and Irving Lottier.

Guest Present: Bethany DiPaula, Mike Nicholson, Howard Schiff, Catherine Putz, Jack Freedman, Kathryn Lavriha, Mike Johansen, Dorothy Levi and Nathan Gruz.

Recusals

President Ades asked that any member of the Board having a conflict of interest relating to any item on the agenda notify the Board at this time.

There were no recusals.

Approval of Minutes

Page two (2), under Meeting with BPQA, second paragraph, third line, change "Assistance" to "Assistant". Page seven (7), under Pharmacy Practice Committee, sixth line, change "all of" to "some of". Page nine (9), under Budget Committee, first and third sentence, add the word "thousand" after seventeen, also, fifth line should read, "savings of nine thousand and seven hundred (\$9,700) dollars for part-time" instead of "nine hundred and seven thousand dollars for part-time."

A motion was made by Ms. Hawkins to approve October 20, 1999 minutes as amended. The motion was seconded by Dr. Love, with a unanimous decision from the Board.

Executive Directors Report/Executive Committee Report

Office Space Report -

Mr. Rubin reported that the Dental Board will be relocating to Spring Grove soon, and the Board will hopefully be able to expand its space in January, although, there may be a delay of up to 3 months.

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Status of new hires -

Mr. Rubin reported that Personnel approved the change in classification of the Executive Director's position and that the position has been advertised in the newspapers. Monday, November 22, 1999 is last day that applications will be accepted for this position. The position is considered as a Special Appointment which means that prospective candidates do not need to be on the State's list. Mr. Rubin explained that the Office of Personnel will classify the applicants as Best Qualified, Better Qualified, or Qualified. The Board then could consider any perspective candidates who were qualified or better. Mr. Rubin reported that the position to assist the PCO may be converted to a non-pharmacist position. The Legislative Officer position has not been filled. Anna Jeffers, Regulation Legislation Specialist, Board of Social Work, has been helping the Board with its regulations. The Data Base Technician position has been filled by Arthur Rolle.

Mr. Rubin stated that by next week, the Board may be reprimanded by the Department of Health & Human Services (DHHS) for not being in compliance with the Healthcare Integrity and Protection Data Bank HIPDB by November 22, 1999. The Board's new Data Base Technician, Arthur Rolle is currently working on this data bank. Mr. Rubin stated that NABP has suggested that Boards use their own judgements about complying.

Mr. Rubin reported that the Board's Licensing Unit is currently short one staff person. The Board is considering Chimes as an alternative hiring source. The position is primarily data entry.

Department proposed legislation -

Mr. Rubin reported that proposed Departmental legislation included rescheduling Marinol from Schedule II to Schedule III. The Board, as well as DDC was a target of a write in campaign by physicians to help facilitate the rescheduling since DEA has already made that change, and Maryland pharmacists must obey the more stringent law.

Mr. Rubin reported that the Board of Physician Quality Assurance is proposing a special purpose license for physicians to practice telemedicine on the Internet. Mr. Rubin stated that this might allow BPQA to protect the public in the same way that the Board of Pharmacy's uses the non-resident pharmacy permit.

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Project Overview -

Mr. Rubin reported on a report he received from the Drug Enforcement Administration (DEA) that there are a number of pharmacists and pharmacies in many states who are using Electronic Data Interchange (EDI) technology to transmit prescriptions for non-controlled substances. This system can not be used for Schedule II substances. This report stated that DEA is working with the Department of Veterans Affairs (VA) to determine the effect of allowing Schedule II electronic transmission. And, is also working with the Performance Engineering Corporation (PEC) to develop the design for a Pilot PKI based electronic prescription system to automate the prescribing of controlled substances.

Mr. Rubin reported that the MPHA Mid-Year Conference will be held February 5 and 6, 1999. Mr. Rubin stated that the Board needs to decide and vote on whether it would like to rent a booth for this conference and the yearly June's Convention. The cost of the booths are three hundred and fifty dollars (\$350) for each meeting. David Russo made a motion for the Board to rent a booth at the MPHA Mid-Year Conference and the yearly June's Convention. The motion was seconded by Dr. Love, with a unanimous decision from the Board.

Guest Presenter

There was no guest presenter.

Board Counsel's Report

Mr. Ballard reported on a draft letter from the Attorney General's Office explaining assisted suicide. The letter explains that the Maryland Legislature recently enacted a new law on assisted suicide. The Attorney General would like to be certain that all pharmacists in Maryland have the proper information about what this bill does and does not do. The new law, known as Senate Bill 319, went into effect October 1, 1999. This law makes assisted suicide a felony punishable by fine and imprisonment. President Ades suggested placing this letter in the Board's newsletter. Dr. Love suggested that since the Board is getting its own Web Site, to post this information on the Web Site. Mr. Rubin stated that he and Ms. Banks will report on the Web Site at a later date.

Committee Reports

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Reciprocity list of candidates -

Mr. Dyke reported that there were twelve (12) candidates who attended the reciprocity meeting held on November 16, 1999. The names are as follows: Adenike Adesina, Shantelle Ballard, Rudolph Choich, Jr., Mary Elliott, Daniel Gmys, Roger Hoover, Monika Houston, Moses Izuegbu, Hyon Kwon, Bach Nguyen, Barbara Sanchez and Eric Strauss. Mr. Dyke motioned to accept these candidates for reciprocity. The motion was seconded by Ms. Hawkins, with a unanimous decision from the Board.

Correcting renewal year for licenses on wrong cycle -

Mr. Dyke reported that the Licensing Committee met on November 4, 1999, at which time several issues were discussed. Mr. Rubin reported that at the last Board meeting the Board discussed the twenty (25) applicants who had licenses issued for the wrong expiration year (decided by odd/even dates). The Board decided that regulations be established to allow a correction for those licensees. This would require that some persons renew one year before they normally would, and the Board agreed to offer relicensure at no charge, although, it is possible that the HCACC fee would have to be charged. Mr. Rubin stated that after analyzing this decision, that it would not be appropriate for the Board to issue a renewal at no charge. Mr. Rubin suggested that it would be appropriate to charge the full fee for the renewal period and require only fifteen (15) CE's for those affected by this error. Had the error not been made, the affected pharmacists would have had to pay for relicensure in 1999 and 2001. Due to the error, they did not have to apply and pay in 1999, but will have to pay in 2000 and 2001 the same number of fees in either case. Dr. Love motioned to approve Mr. Rubin's decision to charge a renewal fee to those candidates affected by this error and to allow them to submit only fifteen (15) CE's. The motion was seconded by Ms. Furman, with a unanimous decision from the Board.

Mr. Dyke reported that there was a discussion at last week's Committee meeting about the appropriateness of requiring brokers who do not handle products to have a distributor's permit. The committee further discussed whether to issue separate licensure for Brokers or to require a distributor's permit. The Committee recommended the latter. The Board decided that, particularly since the regulation requiring a Distributor Permit mentions Brokers in the definition of a distributor, that the regulation applies to Brokers as well as those who distribute medications. The Board left open the possibility of revisiting this in the future. If so, it would be necessary to provide Drug Control with a means to identify Brokers who would not be allowed to handle products.

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Results of October Examination -

Mr. Dyke reported on the October's Laboratory Examination in which there were eighteen (18) candidates. Twelve (12) candidates passed the examination. Mr. Dyke reported that some of the letters have been sent out to the candidates who had all components of the examination process completed. The Licensing Unit is still waiting on results from the NAPLEX and the Law Examination.

Application for reinstatement of license after five (5) years 1 + month -

Mr. Rubin reported that there was an applicant who requested a reinstatement of his pharmacy license in August 1999, four (4) years and ten (10) months after his expired license. The applicant applied for reinstatement in October 1999, five (5) years and one (1) month after his license expired which, would require, in addition to other requirement, one thousand (1000) internship hours. After a lengthy discussion, the Board decided to waive seven hundred and fifty (750) hours. The applicant would only need to complete two hundred and fifty (250) internship hours. Dr. Love motioned to waive the seven hundred and fifty (750) internship hours and have the applicant only submit two hundred and fifty (250) hours based on the possibility that the Board gave out incomplete information regarding reinstatement. The motion was seconded by Ms. Hawkins, with a unanimous decision from the Board.

Regulation Update -

Mr. Rubin reported that changes to regulations 10.13.04, Label of Prescription Drugs, and 10.13.08, Sale of Needles and Syringes or Other Paraphernalia are scheduled to be published in the Maryland Register in December 1999.

Dr. Love reported that the Format of Prescriptions, Outsourcing and the Delivery of Prescriptions, will be discussed at the next Practice Committee meeting.

One of the Board's guest asked what the general policy is on final regulations relating to implementation after final orders are published. Mr. Ballard stated that when regulations are published in the Maryland Register for the first time, there is a comment period. The second publication is the Final Order. Mr. Johansen requested that the Board allow a longer period between the publishing of the Final Order and the effective date than the 10 days normally allowed. Dr. Love asked if there was a method of deciding a different effective date. Mr. Ballard suggested that these types of inquiries should be referred to Michele Finney, Regulations Coordinator. The Board will do so

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on a case by case basis.

Regulation which would require pharmacies to maintain documentation of medication sold or transferred to other pharmacies -

Mr. Freedman, DDC, reported that there was an incident where a pharmacy had a problem involving a large amount of outdated medication, which was not at the pharmacy in the previous inspection. Mr. Freedman suggested that there should be a Regulation regarding the transferring of drugs from one pharmacy to another, which would require a record of the transfers. Mr. Freedman suggested that this issue should be discussed at the Practice Committee.

Ms. Putz, DDC, stated that there is a current investigation regarding a report that drugs are being returned to pharmacies and are being reused. Ms. Putz stated that there are pharmacies involved in this practice and that requiring a record of drugs transferred from other pharmacies would help when doing audits and investigations.

PEAC (Pharmacists Education and Assistance Committee) -

Ms. DiPaula, PEAC Representative, reported that they have twenty (20) current cases, including six (6) new cases. PEAC is working on recruiting new members. The committee has developed a new Continuing Education program. This program will identify individuals who might have a substance related disorder. Ms. DiPaula stated that one of PEAC's main goals is to meet with some of the key members of chain pharmacies in order to identify pharmacists who may have a problem in this area. Ms. DiPaula reported that Ms. Norene Pease has volunteered to join PEAC.

Pharmacy Practice Committee -

Mr. Rubin reported that there was an special meeting of the Unlicensed Personnel Task Force held on November 4, 1999, in response to issues raised by the Joint Legislative Committee on Healthcare. Mr. Rubin reported that one of the committee's concerns with the proposed regulations is that they feel that the Board should specify training programs for unlicensed personnel. Mr. Rubin presented to the Board a draft regulation of (10.34.10A) Standards of Practice-Unlicensed Personnel, for its review. This draft reflects changes made in response to the Legislature's concerns. Mr. Rubin indicated that there has been a *new section* placed in these regulations, item number .03f. This particular section requires that the permit holder "*documents the training required to allow unlicensed personnel to perform functions in that segment of the prescription process in which they will participate.*"

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Dr. Love suggested deleting the word *orally* in section .04B2, which specifies acts that the unlicensed person may not participate in. Dr. Love stated that there is concern about the unlicensed person retrieving prescriptions received electronically and beginning to process them without the pharmacist reviewing them first. This would be the same concern as when the unlicensed person accepts prescription orally. Dr. Love stated that the key word in section .04B2 is ACCEPTING as opposed to retrieving in which accepting implies that a decision has been made and that the order is valid. Dr. Love stated that if an unlicensed person alters a prescription that comes in by fax, it is detectable. Dr. Love further stated that if an unlicensed person receives a prescription that comes in orally, they could mistranscribe that prescription. After a lengthy discussion, Mr. Rubin suggested that this matter be sent to interested parties for review and comment and that the Board would revisit this issue when concerns were received. Request for comments will go to State pharmacy groups, certain other Boards, and others.

Automation Task Force -

Ms. Furman reported that the committee met on October 12, 1999. Ms. Furman stated that Dr. Love is working on some of the wording/language for the regulation of automation. One area of concern is the use of matrix drawers, including the ability of Certified Medication Aids to access the drawers. Ms. Furman stated that the Committee will be ready to present to the Board the proposed regulation. Ms. Furman stated that the matrix drawer issue will be discussed at the next Practice Committee meeting. Ms. Furman recommended having some of the members from the Task Force Committee attend the Practice Committee Meeting so that everyone's view can be taken into consideration.

Medication Error Prevention Project -

Dr. Love reported that at the last Practice Committee meeting, the Committee discussed this issue and offered some direction to the Task Force Committee. The directions were not to try and implement a centralized reporting system but to mandate a quality improvement system to address medication error tracking which permit holders would have to establish. Dr. Love stated that he would like permit holders to address this issue. Dr. Love also suggested random auditing.

Narrow Therapeutic Index Drugs -

Ms. Schneider reported that Mr. Rubin has set up a meeting with Dr. Benjamin to take place on Thursday, December 2, 1999, at 301 W. Preston Street, Baltimore, MD 21201.

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related to Narrow Therapeutic Index Drugs which certain manufacturers want to remain classified as drugs which the pharmacist may not interchange without prescriber approval. Mr. Rubin reported that representatives from the School of Pharmacy and Board of Pharmacy will attend this meeting.

Local Health Department P & P for Registered Nurse Dispensing -

Dr. Love reported that a majority of the Pharmacy Practice Committee who met on November 2, 1999, discussed the policy on medication dispensing. Dr. Love stated that policies and procedures are being worked on to allow nurses to dispense at local Health Departments under certain circumstances. Dr. Love stated an effort to do this by legislation was defeated. The local health department nurses then asked BPQA to allow physicians to delegate this authority. This will be granted once a health department policy that governs this issue is in place. Dr. Love stated that, thus far, there have been seventeen (17) drafts of this policy. The Committee commented informally on many of the drafts to try to get safeguards in place, including an oversight committee that would not be dominated by any one profession. Dr. Love suggested that Ms. Andoll would incorporate the safeguards into documentation form for the next Practice Committee meeting. Once the changes are made the committee can present them to the Board members to make decisions regarding this issue.

Confidentiality Issues Regarding Waste Disposal From Pharmacies -

Dr. Love reported that the committee discussed inquiries from the Board from WBAL Television Station regarding their recent topic on finding confidential information in the form of disregarded labels and notes in dumpsters and other garbage disposed from pharmacies. Dr. Love stated that the Committee did not feel that consideration of regulations is necessary. The Committee asked the Board to inform permit holders and licensees of their obligations to confidentiality, including shredding or disposing in some other way that would not allow public access to confidential information in waste. The committee also recommended this matter be placed in the Board's newsletter. Mr. Schiff stated that Neighborcare has given each of their pharmacies a shredder.

Board Asked To Consider Task Force To Review Statutes And Regulations As They Will Apply To Pharmacy In The Next Decade -

Mr. Rubin reported that the Board has worked on numerous regulations which address changes which are coming about in the profession and asked the Board to consider having a task force to review all statutes and regulations to see how they apply to Pharmacy in the next decade. This would not start until at least early next year.

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Dr. Love stated that the next Practice Committee meeting will be held December 1, 1999, at The Board of Pharmacy, 4201 Patterson Avenue, Baltimore, MD 21215, at 4:30p.m.

Public Relations Committee/Counsel of Boards Report -

Mr. Rubin reported that he will meet with the Board of Public Works on Monday, November 29, 1999 to discuss the Media Campaign Contract. Mr. Rubin reported that the Board had one hundred and fifty thousand (150,000) brochures printed and approximately one hundred and forty thousand (140,000) have been sent out to the general public, such as churches, government buildings, senior citizen buildings and libraries, etc.

Unlicensed Personnel Brochure -

Mr. Rubin reported that the Board sent out letters to the Epic Pharmacy and the large chains to solicit their support in getting these brochures out to the public. The Board has only received one response thus far from the chains, from Safeway Pharmacy.

Internet Site -

Mr. Rubin reported that Ms. Banks is currently working on setting up this site. The information to be placed on this site has not been approved by Counsel. The committee is working on drafting a mission statement to be placed on this site.

Budget Committee -

Mr. Rubin reported that the Board will accrue a large surplus this year due to vacant positions.

Question For The Board

Can The Board Provide A Card For Retired Pharmacists -

The Board did not make a decision regarding this issue.

Meeting Adjourned at 11:00 A.M.

Respectively Submitted,

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W. Irving Lottier, Jr.,
Secretary

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